

REMARKS

In the Office Action, claims 1-22, 25-43, 46-47 and 55 were examined in light of Applicant's election of species and amendment. Claims 3-5, 14, 17, 27, 29-37, 46, 47 and 55 were withdrawn from consideration. Claims 1-2, 6-13, 15-16, 18-22, 25-26, and 28 were provisionally rejected for alleged nonstatutory obviousness-type double patenting over claims 1, 2, 6-13, 15, 16, 18-26, and 28 of copending Application No. 10/600,286 (now allowed). Claims 1-2, 6-10, 12-13, 15-16, 18-22, 25-26 and 28 Claims 1-2, 6-10, 12-13, 15-16, 18-22, 25-26, 28, 39 and 42 were rejected under 35 USC 102(a) over Gaylord et al. (PNAS, Aug. 20, 2002, vol. 99, no. 17, p. 182) ("Gaylord"). These rejections are traversed. Consideration of product by process claims 42, 43, 46 and 47 is respectfully requested, as these depend on method claims under consideration and believed allowable, and incorporate all the limitations thereof.

Request for Telephonic Interview

A telephonic interview is requested prior to the issuance of a subsequent Office Action should any issues remain after entry of this response that would delay allowance of the claims. The undersigned may be reached at (858) 228-7829.

The provisional double patenting rejection

Claims 1-2, 6-13, 15-16, 18-22, 25-26, and 28 were provisionally rejected for alleged nonstatutory obviousness-type double patenting over claims 1, 2, 6-13, 15, 16, 18-26, and 28 of copending Application No. 10/600,286 (now allowed).

To establish obviousness, all claim elements must be contained in the cited reference(s). For an obviousness-type double patenting rejection, only the claims of the cited patent may be used to establish obviousness; the specification may not be used.

Burden of procedure. "The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Rijckaert*, 9 F.3d at 1532, 28 USPQ2d at 1956. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be

overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).” *In re Deuel*, 51 F.3d 1552, ___, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

Criteria for establishing *prima facie* obviousness. “To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” MPEP 2142. The motivation in the prior art to modify or combine references must be clear and particular. *In re Dembicza*k, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999). “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).” MPEP 2143.01.

All claim elements are not present in ‘286 because the ‘286 claims do not teach or suggest an anionic sensor polynucleotide as claimed. The claims of the ‘286 application deal with a sensor peptide nucleic acid (PNA), which is not anionic. The pending claims, by contrast, all relate to a method using an anionic sensor polynucleotide. Therefore, the ‘296 claims do not teach or suggest all the claim elements, as is required to establish obviousness.

No reasonable expectation of success exists in modifying the ‘286 claims to reach the claimed invention. The ‘286 claims relate only to the use of PNA sensor polynucleotides. The methods in those claims involve the recruitment of the sensor PNA to the vicinity of the polycationic multichromophore through use of electrostatic interactions with a bridging target polynucleotide. Those methods thus involve a lower background signal than present in the current methods, because the PNA sensor does not associate to a significant degree with the

polycationic multichromophore in the absence of the target, which links the two to permit efficient energy transfer between the multichromophore and the signaling chromophore which is conjugated to the sensor.

In the claimed methods, the anionic sensor polynucleotide already associates with the cationic multichromophore even in the absence of target, and energy transfer *can already occur*. The surprising result of the inventors' experiments in such a system was that it is possible to show an increase in signal when the target is present, *even though the anionic sensor does not need the target to associate with the multichromophore*.

It could not have reasonably been expected from the claims of '286 that an increase in signal could occur using an anionic sensor polynucleotide to detect a target polynucleotide using energy transfer between a polycationic multichromophore and a signaling chromophore conjugated to the sensor. Given that the sensor in the claimed method associates with the multichromophore in the absence of target, one of skill would have reasonably believed that the claimed method would not exhibit an increase in signal in the presence of target. Thus one of skill would not have had a reasonable expectation of success that the method of the '286 claims could be modified towards the pending claims.

The claimed invention is not obvious over the '286 claims, and therefore nonstatutory double patenting is not present. As all claim elements are not present in the '286 claims, and there was no reasonable expectation of success in modifying the '286 claims to reach the claimed invention utilizing an anionic sensor polynucleotide, obviousness of the claims over the '286 claims has not been established.

Withdrawal of the obviousness-based provisional nonstatutory double-patenting rejection is therefore respectfully requested, as the claims are not obvious over the '286 claims.

The Rejection over Gaylord

Claims 1-2, 6-10, 12-13, 15-16, 18-22, 25-26, 28, 39 and 42 were rejected under 35 USC 102(a) over Gaylord et al. (PNAS, Aug. 20, 2002, vol. 99, no. 17, p. 182) ("Gaylord").

To establish anticipation, all claim elements must be present in a single reference.

Gaylord discusses methods utilizing a PNA sensor polynucleotide, as described above in relation to the '286 patent application. As set forth above in relation to the '286 application, Gaylord's methods neither teach nor suggest the use of an anionic sensor polynucleotide as claimed.

Furthermore, as described above, there is no reasonable expectation of success that Gaylord's methods could be modified in this way.

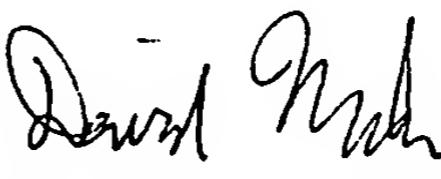
As all claim elements are not present in Gaylord, Gaylord cannot establish anticipation.

Withdrawal of the rejection is respectfully requested.

CONCLUSION

As the claims are believed in order for allowance, a notice to that effect is respectfully requested. Should any issues or questions remain after entry of this response, a telephonic interview is requested prior to the issuance of a subsequent Office Action so that any remaining issues can be discussed. The undersigned may be reached at (858) 228-7829.

Respectfully submitted,

By: 

David W. Maher, Ph.D.

Reg. No. 40,077

David W. Maher, J.D., Ph.D.
BioTechnology Law Group
527 North Highway 101, Suite E
Solana Beach, CA 92075-1173
Phone: (858) 228-7829
Fax: (858) 350-9691
david@biotechnologylawgroup.com